Bandolier 49

What do we think?
What do we know?
What can we prove?

Evidence-based health care **£3.00** **March 1998 Volume 5 Issue 3**

Not for NHS patients or dogs

"Never in the history of the human race were physicians and scientists using their brains to such good advantage as at the present day. The stumbling blocks which have existed....are being surmounted with amazing rapidity, and disease is in the act of rapidly succumbing to the progress of science". Sounds contemporary, but found in a booklet coming with Dr Macaura's marvellous invention (circa 1930s) called The Pulsocon (Patent number 13932).

The booklet says that the Pulsocon cures everything - pain, deafness, anaemia, impotence, "womens' problems", the lot. The logic, quoting Hippocrates, is that of massage. But while a human can only achieve 400 percussive strokes a minute, if you paddle this device fast enough you can get up to 2,000 a minute. A classic technology creep argument.

Inside the box was a little handwritten note, with the compliments of the inventor, which says "unsitable for use in NHS patients or dogs". ***Bandolier*** would love any information on the logic of this, and a date for it.

Testing times

Devices and diagnostics seem to be under less stringent rules than pharmaceuticals. Perhaps there are lessons to be learned from the news on hip prostheses. How do you know whether a prosthesis loaded with bells and whistles will outperform a standard prosthesis?

In Sweden they order these things differently, with comprehensive prospective audit in a number of areas - hip prostheses being one. The result is that failures are picked up very quickly.

Unknowable things

Some things may be truly unknowable. How long might anthrax spores left in the ground retain their viability? A difficult one. What irritates is those circumstances where we should know but don't. This month ***Bandolier*** examines ejaculation and PSA. The only reason that men have a prostate gland is because of ejaculation, so there should be a simple and clear answer, yes? No - few studies, and despite huge numbers of papers on PSA there is still no clear answer.

Knowing things

When things that should be known are known, life is simple. Some good examples this month include another in the growing list of radiology prediction rules from Ottawa, this time for ankles. Others include accumulating evidence on the use of tests and benefits of treatment in HIV, and the uselessness of enzyme supplements in pain with chronic pancreatitis.

Privy poesy

Isn't it strange how matters lavatorial are so interesting? So here is a poem on the subject by a man who is reputed to be the most obscure of the 18th century poets (but how do you know there isn't someone even more obscure?). Positively no more on the subject unless it is a good trial or review.

Privy-love for my Landlady

Here costive many minutes did I strain,
Still squeezing, sweating, swearing, all in vain;
When lo! who should pop by but Mother Masters,
At whose bewitching look soon stubborn arse stirs.
No more my wanton wit shall whip thy wife,
Dear, doting Dick, for O! she saved my life.

George Farewell (1733) in The New Oxford Book of Eighteenth Century Verse (ed Roger Lonsdale).

In this issue

OTTAWA KNEE RULE OK

In previous issues of ***Bandolier*** we have given information about the Ottawa ankle rules - a set of clinical decision rules for helping to decide when someone with an ankle injury needed an X-ray to see if there was a fracture. That the ankle rule worked was demonstrated in a number of studies. Evidently working up the body, they now give us the Ottawa knee rule to determine whether a knee injury needs an X-ray. The knee rule is given in the box below.

Making the knee rule

The way the rule was determined is interesting. Over 1000 knee injury patients were assessed for 23 standardised clinical findings. Those variables found to be most reliably and strongly associated with a fracture were subjected to statistical analysis. These were then incorporated into the rule.

Testing the knee rule

Four hospitals in Ontario were chosen. Two were control hospitals where no intervention was made. Two were intervention hospitals. The knee rule was introduced by means of a brief lecture, a pocket card, and wall posters in the emergency department. Staff were given regular updates of progress and difficulties in implementing the rule.

Eligible patients were those seen in the twelve months before and after the introduction on the rule. Clearly not all patients would be eligible and, for example, patients younger than 18 or those with major trauma were not regarded as suitable candidates for use of the decision rule.

Results

About four thousand people (3,907) were seen with knee injury in the four hospitals over the two periods. The main result was the proportion sent for X-ray. This was an average of 26% lower in the intervention hospitals after the introduction of the knee rule compared with previously (Figure). Control hospitals showed no change.

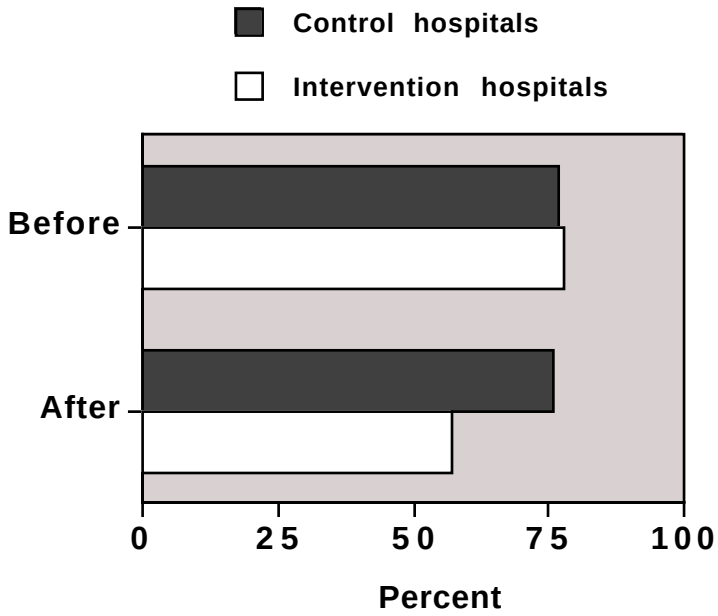
The knee rule correctly predicted all the fractures. No patient who did not have an X-ray was found subsequently to have a fracture.

Ottawa knee rule

A knee X-ray series is only required for knee injury patients with ***any*** of these findings:

1. Age 55 or older
2. Isolated tenderness of the patella (that is, no bone tenderness of the knee other than the patella).
3. Tenderness at the head of the fibula.
4. Inability to flex to 90 degrees.
5. Inability to bear weight both immediately and in the emergency department (4 steps; unable to transfer weight twice onto each lower limb regardless of limping).

Percentage of patients with knee injury having knee X-ray in:



Time spent in the emergency department, time spent off work, and overall medical costs were lower (by US$103 per patient) in those who did not have an X-ray than those who did.

Comment

Yet another superb example of how to do a diagnostic test and show it works. The process they describe is so simple (compared with a typical randomised trial of a therapy, for instance), that it is perplexing that it is not used more frequently in clinical (and clinical plus laboratory) diagnosis. Because the knee rule is tested (as here), or as the ankle rule has been tested more than once, and shown to work, we have excellent evidence that we are doing the right thing. And while each in themselves makes only a small change in practice, the combined effect adds up to make a real difference.

Reference:

1 IG Stiell, GA Wells, RH Hoag et al. Implementation of the Ottawa knee rule for the use of radiography in acute knee injuries. JAMA 1997 278: 2075-9.

Clinical Effectiveness in Mental Health:
Tuesday 19th May, 1998,
Commonwealth Institute, London

The Royal College of Psychiatrists' Research Unit is organising a one day multi-professional conference entitled 'Clinical Effectiveness in Mental Health: Practical Approaches to Real Problems'. It will take a practical approach in recognising problems face by mental health services in their efforts to become more effective. Keynote speakers are Paul Boateng MP and Dr Jenny Firth-Cozens. CPD accreditation has been sought.

Further information from: Victoria Thomas, College Research Unit, 11 Grosvenor Crescent, London, SW1X 7EE. Tel: 0171 235 2351 x 273. Fax: 0171 235 2954. Email: victoria.thomas@virgin.net.

Chronic pancreatitis

Chronic pancreatitis is uncommon (perhaps 20 cases per 100,000 population). Problems are pain and steatorrhoea, and the treatment of choice advocated by well-known textbooks is pancreatic enzyme supplementation. A new meta-analysis of the use of enzyme supplements to reduce pain [1] shows them to be without effect.

Searching

The search was not exhaustive. Only MEDLINE was searched, and only English language papers used.

Results

All studies included were of a randomised, double-blind crossover design, and of two weeks to eight months duration. There were six studies, with a total of 189 patients, with six different pancreatic enzyme supplements. Pain scoring methods seemed sensible.

Only one trial of the six showed a statistical improvement over placebo as judged by patient preference - that of the two-week duration (Figure). Overall the relative benefit was 1.2 (95% confidence interval 0.8 to 1.8).

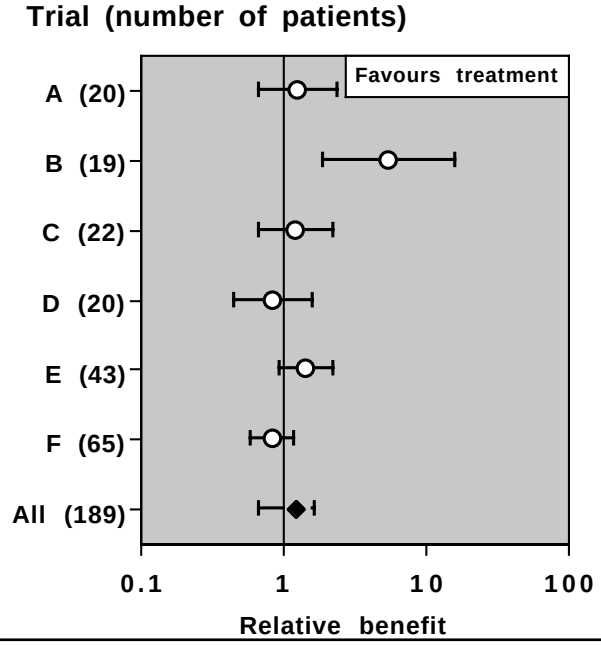
Comment

While the search strategy employed for this meta-analysis was sub-optimal, the results were consistent: pancreatic enzyme supplementation is not judged to be effective by patients.

Reference:

1 A Brown, M Hughes, S Tenner, PA Banks. Does pancreatic enzyme supplementation reduce pain in patients with chronic pancreatitis: a meta-analysis. American Journal of Gastroenterology 1997 92: 2032-5.

Randomised, double-blind, crossover studies of pancreatic enzyme supplementation in decreasing pain in chronic pancreatitis



Cod piece: evidence-based eating

In the USA there are about 250,000 sudden cardiac deaths each year, and in over half the cases there was no prior history of heart disease. Only 30% of people with cardiac arrest who reach hospital will be discharged alive. A paper suggests that eating one portion of fish a week reduces the risk of sudden cardiac death substantially [1].

Friday is fish

As part of the Physicians' Health Study male US physicians aged 40 to 84 years in 1982 were studied. Twelve months into the study they filled out detailed questionnaires on how often they ate fish, and of what type. They were then followed up to the end of 1995. Sudden death was defined as death within one hour of symptom onset, a witnessed cardiac arrest, or both, or abrupt collapse not preceded by more than one hour of symptoms that precipitated the terminal event.

Results

There were 20,551 men with eligible data of whom 3% ate fish rarely or never and 11% ate fish more than five times a week. Compared with those who ate fish rarely, eating fish at least once a week reduced the risk of sudden cardiac death by 52% (95% CI 4% to 76%). There was no effect on myocardial infarction or other cardiac endpoint.

Pick the bone out of this

Fish consumption may not reduce heart attacks, but it can cut the chance of surviving one substantially. It doesn't matter what sort of fish, and eating more than one portion a week confers no extra benefit. The mechanism, hypothetically, is some anti-arrhythmic effect of fish fatty acids.

Reference:

1 CM Albert, CH Hennekens, CJ O'Donnell et al. Fish consumption and risk of sudden cardiac death. JAMA 1998 279: 23-8.

Outcome after hip fracture

Bandolier previously reported on prevention of falls in the elderly (issue 20), and on the first report of the East Anglian Audit on hip fracture (issue 25). A follow-up report tells us the consequences of a broken hip at 90 days [1].

Briefly, the audit examined all patients admitted with fractured neck of femur in eight hospitals in a period in 1992. Patients were interviewed in hospital soon after admission and at three months about activities of daily living, residential status and use of community services.

Results

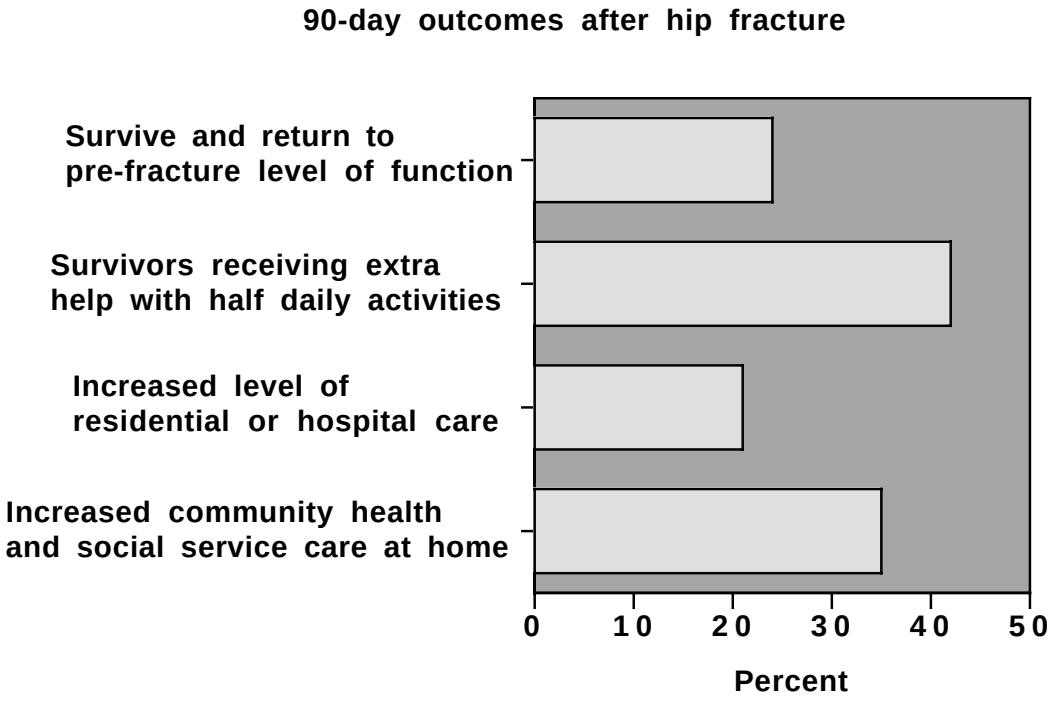
Data were available on 580 patients. The overall 90-day mortality was 18%.

- Fewer than a quarter of patients both survived and returned to their pre-fracture level of function by 90 days.
- Of survivors, less than one-third returned to their pre-fracture level of function.
- Of survivors, 42% were receiving extra help with at least half of their daily living activities.
- Of survivors, 21% required an increased level of residential or hospital care.
- Of patients who returned home 35% required additional community health and social service visits.

Comment

Real data, together with some interesting analysis on those features which may help to make outcomes better.

Reference:
1 C Laxton, C Freeman, C Todd et al. Morbidity at 3 months after hip fracture: data from the East Anglian audit. Health Trends 1997 29: 55-60.



Old curiosity shop

Why do we take flowers to someone in hospital? Grapes, yes - something for the visitor to eat. But flowers? They just look nice. But perhaps that is the point. For a person stuck in a hospital bed something nice to look at may be just the ticket. This was demonstrated by a classic retrospective study which investigated whether the view through a window influenced recovery from surgery [1].

Study

Patients undergoing cholecystectomy in a Pennsylvania hospital had postoperative care on one of two floors, with rooms which looked at either a brown brick wall, or a small stand of deciduous trees. Rooms were essentially identical apart from the view, and records were only examined for the period in the year when there were leaves on the trees.

Patient records were matched for all sorts of possible confounding factors, and then the 23 pairs of patient records were given to an experienced nurse to abstract information on number of days in hospital, analgesic and drug history, complications, and nurses' comments on patients' wellbeing.

Results

Patients with the tree view spent one day fewer in hospital, used predominantly oral analgesics after the first day (and had less than half of the number of injections), and had many fewer negative comments on their postoperative progress from nurses caring from them (1 per patient compared with 4 per patient for the brick wall view). All these were statistically significant at the 1 in 100 level. Postoperative complications were lower in tree view patients, but not significantly so.

Comment

'Overall package of care' is one of those interesting comments one sees in reports of all sorts. Very often we try to untangle the package to see which of its components is important - but if we don't know what is important, how do we know what to test?

This is a problem in all sorts of circumstances, but a result like this is quite possibly transferable to other situations. We know that patients of friendly dentists do better, so what about those who have flowers in hospital?

Reference:
1 RS Ulrich. View through a window may influence recovery from surgery. Science 1983 224:420-1.

HIV AND AIDS

The report of the ***Bandolier*** conference is now available. It can be found on ***Bandolier***'s web pages, or can be obtained from Eileen Neail by fax on +44 1865 226978. Some new information reinforces the evidence that plasma viral load predicts eventual outcome and is a useful surrogate marker, and that the newer combination therapies make a real difference in real practice.

Viral load and CD4 predict outcome

A study [1] of 664 seropositive injection drug users over eight years allowed the correlation of viral load (number of copies of HIV nucleic acid per mL of blood) and CD4 cells at diagnosis with eventual outcome of progression to AIDS and/or death due to an infectious disease. Of the 664 enrolled subjects 522 had sufficient samples from the initial diagnosis to allow the viral load test to be performed.

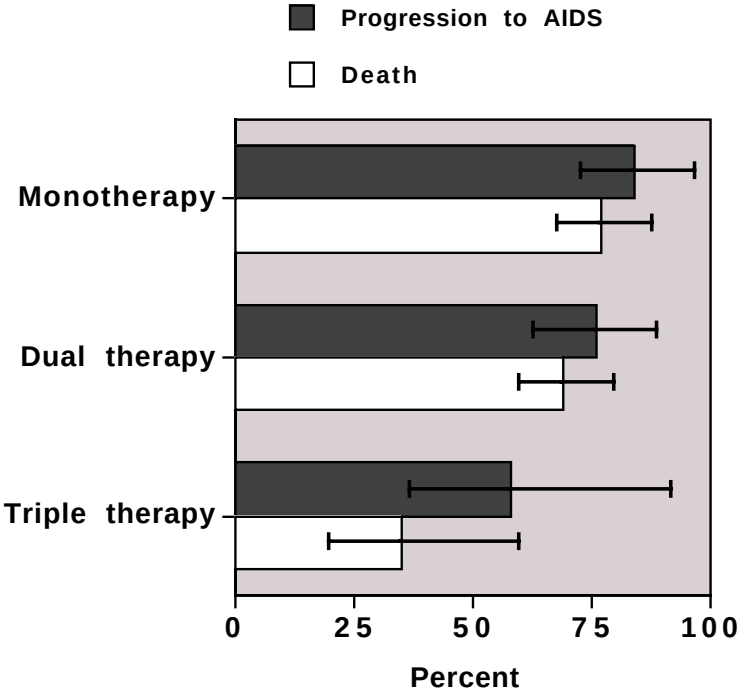
The results (Table) show an interplay between the two diagnostic factors. People with low CD4 counts and high viral loads do badly over a five-year follow up. Those with high CD4 counts and low viral loads do well. The evidence on the importance of HIV viral loads as a prognostic factor is accumulating (***Bandolier*** 41).

Combination therapies reduce disease progression

One of the questions posed about clinical trials is whether the results will be the same when the intervention goes into clinical practice. Arguments that they may not include different patient characteristics between trials and everyday practice, and treatment schedules in everyday practice not being the same as those used in clinical trials. An observational prospective study that included a large proportion of HIV-infected patients in Switzerland [2] indicated that, for HIV treatments, inclusion of new treatments in everyday practice produces startlingly good results.

The study involved 5200 participants enrolled since 1988. Since 1988 the proportion of patients having no treatment has fallen, with concomitant increases in patients having dual therapy (two antiretroviral drugs) or triple therapy (two antiretroviral drugs plus a protease inhibitor). The results (Figure) show that the use of more aggressive therapies led to reduced risk of progressing to AIDS and death. Even though the 95% confidence intervals in the Figure are wide for triple therapy, the trend is all in the right direction and is in accord with the results of randomised trials (see ***Bandolier*** 44).

Effects of type of therapy on risk of disease progression and death compared to no treatment (Swiss prospective cohort study)



References:

1 D Vlahov, N Graham, D Hoover et al. Prognostic indicators for AIDS and infectious disease death in HIV-infected injection drug users. JAMA 1998 279: 35-40.

2 M Egger, B Hirschel, P Francioli et al. Impact of new antiretroviral combination therapies in HIV infected patients in Switzerland: prospective multicentre study. BMJ 1997 315: 1194-9.

Five-year outcomes of progression to AIDS or infectious diesease death according to CD4 and virus concentrations in blood

	CD4 cell count					
	CD4 <200/µL		CD4 200-490/µL		CD4 ≥500/µL	
Viral load (coplies/mL)	AIDS (%)	Infectious disease death (%)	AIDS (%)	Infectious disease death (%)	AIDS (%)	Infectious disease death (%)
<500			8	0	0	0
500-9999	58	14	12	7	9	5
10,000-29,999	75	75	35	16	11	4
≥30,000	83	76	42	32	23	15

Making sense of PSA and ejaculation

What is the prostate gland for? Its principal physiological function is to manufacture the fluid that nurtures spermatozoa. What happens to one of its principle prostate-specific proteins in serum upon ejaculation might seem a sensible first step in sorting out the use of a serum test. Given that PSA is often measured, that thousands of papers are published on PSA each year, and millions of tests done, one might think that the effects of basic physiological changes would be well sorted out. Not so.

When an assay is just a guess

To answer the question about the effect on PSA of ejaculation, it is necessary to enter the arcane world of immunoassays and their properties.

Any assay is designed to measure something within certain concentration limits. For most common PSA assays, this means values between about 1 to 100 μg/L. Samples with higher concentrations can be diluted to be within this range. But concentrations of less than 1 μg/L are in a part of the assay where significant inaccuracies can be expected, and below about 0.5 μg/L any value obtained is little better than a guess (though there are some 'super-sensitive' assays which can measure very low values). Many of the articles examine populations with very low PSA levels.

What is the question?

PSA will be measured in many clinical situations (like after operation for prostate cancer) where ejaculation is unlikely to be an issue. But where prostate cancer is just a suspicion a serum PSA might well be part of the diagnostic regimen in a man who is sexually active. Knowing whether and how ejaculation affects serum PSA will be important. We are most concerned with effects in older men (over 50) who have, and who do not have, prostate cancer or benign hyperplasia, because these are the people most likely to be tested. How long after ejaculation do any effects last? That will affect the interpretation and usefulness of the test.

Many articles look only at young men, and at times early after ejaculation. Those that look at older men generally exclude those with prostatic disease.

Where's the evidence?

Bandolier performed a MEDLINE search for papers which examined ejaculation and serum PSA. We found nine. The details are shown in the Table. None of the articles commented on the ability of the assays used to measure low values of PSA.

In order to help sort wheat from chaff, we made a decision as to whether the studies were valid or not. Invalid articles were defined as those which had only men with very low serum PSA concentrations (less than 0.6 μg/L), those which made no statement about abstinence from intercourse before the study, or those which had measurements only at very short times after ejaculation. Four studies were invalidated by these criteria. For the remaining five, the results can be looked at by age (we chose an arbitrary cut off of about 40 years) and by PSA concentration.

Younger men

All the studies had men with very low PSA concentrations. Of the two valid studies, one showed a large decrease at one day, and one showed no change. One study invalidated because of no stated abstinence period before the study started also showed large decreases in all men with PSA values above 1 μg/L over five days.

Older men

None of the studies included men with prostate cancer known or suspected and only one included men with higher concentrations of PSA. Three valid studies showed increases or no change in serum PSA after ejaculation. Increases, when seen, tended to be at earlier times (hours rather than days). The study which examined how changes in PSA were related to baseline concentrations demonstrated greater increases with higher baseline values.

Comment

A complicated story which perhaps serves to demonstrate how difficult it is to get a simple answer to a simple question. The variabilities of assay performance, age and baseline PSA concentration have largely been ignored. What seems to be the answer is that there may (*and this is a big may*) be falls in PSA after ejaculation in men below about 45 years over one to five days, but rises in older men. What evidence there is suggests that rises are greater with higher baseline PSA and that they last for perhaps one or two days. We still have no idea of the effect of ejaculation in men with prostate pathology.

Men having blood taken for PSA should be advised to abstain from intercourse for several days before, or at least be questioned about the time since their last ejaculation.

References:

1 WJ Glenski, GG Klee, EJ Bergstralh, JE Oesterling. Prostate-specific antigen: establishment of the reference range for the clinically normal prostate gland and the effect of digital rectal examination, ejaculation, and time on serum concentrations. The Prostate 1992 21: 99-110.

2 R Simak, S Maderbascher, Z Zhang, U Maier. The impact of ejaculation on serum prostate specific antigen. Journal of Urology 1993 150: 895-7.

3 Z Kirkalt, G Kirkalt, A Esen. Effect of ejaculation on prostate specific antigen levels in normal men. European Urology 1995 27: 292-4.

4 A Heidenreich, R Vorreuther, S Neubauer et al. The influence of ejaculation on serum levels of prostate specific antigen. Journal of Urology 1997 157: 209-11.

5 A Zisman, Y Soffer, Y Seigel et al. Postejeculation prostate specific antigen level. European Urology 1997 32: 54-7.

6 JK McAleer, LW Gerson, D McMahon, L Geller. Effect of digital rectal examination and ejaculation on serum prostate specific antigen after twenty-four hours. Urology 1993 41: 111-2.

7 M Tchetgen, J Song, M Strawderman et al. Ejaculation increases the serum prostate specific antigen concentration. Urology 1996 47: 511-6.

8 N Netto, F Apuzzo, E de Andrade et al. The effects of ejaculation on serum prostate specific antigen. Journal of Urology 1996 155: 1329-31.

9 J Herschman, D Smith, W Catalona. Effect of ejaculation on serum total and free prostate specific antigen concentrations. Urology 1997 50: 239-43.

Effects of ejaculation on serum PSA

Reference	Population	Abstinence period	Mean baseline PSA (µg/L)	PSA Method	Post-ejaculation assay times	Results	*Bandolier*'s judgement
Younger men							
Glenski et al, 1992	30 men 22-30 years	not stated	0.55	Tandem-R	1 day	no change	invalid
Simak et al, 1993	18 men 20-39 years	4 days	1.4	Tandem-E	1 day, 7 days	85% fall at 1 day, and about 70% at 7 days	valid
Kirkalt et al, 1995	19 men 21-25 years	none stated	0.75	Tandem-E	1-5 days	no change overall, but men with PSA >1 µg/L all showed falls of ≥ 50% at some time over 5 days	invalid
Heidenreich et al,1997	100 men 25-35 years	4 days	0.85	Tandem	1 hour, 1 day	no change	valid
Zisman et al, 1997	25 men 20-45 years	3 days	0.9	Roche	1 hour	increase	invalid
Older men							
McAleer et al,1993	35 men 40-86 years	none stated	1.74	Tandem -R	1 day	no change	invalid
Tchetgen et al,1996	64 men 49-79 years	7 days	range <1 to 13	probably IMx	1, 6 and 24 hours	increase in PSA, with larger increases for higher baseline PSA	valid
Rodrigues et al,1996	40 men 50-60 years	3 days	1.7	Tandem-R	1 day, 7 days	no change	valid
Herschman et al,1997	22 men 51-67 years	1 day	1.3	Tandem-E	1, 6 and 24 hours	increase at 1 hour, but not 1 day	valid

No report made any statement about analytical accuracy at low levels of PSA

Book reviews

Last night they got the elephant!

Against the Gods. Peter L Bernstein. John Wiley. ISBN 0-471-12104-5. 337pp. UK£17.99.

One night during the Second World War, in one of the many air raids on Moscow, a distinguished professor of statistics appeared in the local air-raid shelter. He had never been there before, because he used to say that there were seven million people in Moscow, so why should he expect to be hit. His friends asked about the change of heart. "Look," he explained, "there are seven million people in Moscow and one elephant. Last might they got the elephant".

That story could be taken as encapsulating all our problems with risk. But there are more than you think. Peter Bernstein's book is a tour-de-force through numbers, risk and how people perceive and respond to it, investment and the way markets work. It is highly readable and full of great quotes.

Best of all, though, is that this book will explain things in ways that are so different that you will understand things you thought beyond you. Bet you don't believe that. Here's a test - hands up all those who think they understand regression to the mean. Not many of you. But go to the chapter entitled "The man with the sprained brain", and you will. It might just change your life if you play the markets.

Being right

Bandolier particularly liked its introduction to the "Law of Large Numbers". A brainchild of Jacob Bernoulli (one of a tribe of gifted philosophers and mathematicians, not the man who invented the disc drive), this is statistics the other way round. Usually statistics tell us how likely a result is to be wrong: the Law of Large Numbers is more concerned about how likely it is to be right.

Think about this for a moment. What do we want with the result from a trial or meta-analysis? Actually we want to know how likely we are to be right, especially if we sit down for a moment to consider just how right we have to be for any particular circumstance. There is a risk with this book: it might change the way you think about research.

Getting the best from the literature

How to read a paper. Trisha Greenhalgh. BMJ Publishing. ISBN 0-7279-1139-2. 192pp. UK£14.95.

In the introduction Trisha Greenhalgh remembers ward rounds with a distinguished professor, whose clinical acumen and memory were second to none. But that had taken 40 years to acquire. Dipping into the medical literature for those of us (the vast majority) who have never done enough research to be familiar with all the nuances and "tricks of the trade" can be a daunting task.

We hear that much research is not scientifically sound. We know that some research can be biased. We don't know how to make sense of a randomised trial compared with a retrospective case series. Sensitivity and specificity of diagnostic tests are beyond us. And statistics - give us a break!

Not any more. No excuses - because anyone with two neurones to rub together can be at least in touch with a modern scientific paper after putting in some time to read Trish Greenhalgh's superb guide to reading and understanding papers and what goes into them. It is an easy read, and an enjoyable one (we *loved* the box on page 70 on how to cheat on statistical tests when writing up a paper, and that on page 88 on how companies sometimes over-egg the pudding when marketing their products).

Bandolier has spent many hours reading, and much harsh handling from trial and error to learn only part of the good common sense that is in this book. It will be useful for the "first-year medical student and the grey-haired consultant". Don't just take our word - those are the words of Professor Sir David Weatherall in the foreword!

Searching for evidence

Gwent used to be famous as the long-lasting bastions of Romano-British culture, and latterly for the Pontypool front row (a different sort of culture). A new reason for it to be famous is the TRIP database (http://www.gwent.nhs.gov.uk/trip/) which is a one-stop search engine for evidence-based material on the Internet.

There are hyperlinks to ***Bandolier***, to the Cochrane database, Evidence-Based Medicine and many others. The clever feature is that you need to enter only one search engine to search a number of great databases - and the site is growing in power all the time. The number of searchable hyperlinks is over 1100, and growing.

Bandolier found the TRIP database highly user friendly (if a bit garishly coloured). For those on the Internet who want to find evidence fast, this is an excellent way in and a quick way of finding out if there is something you can get to ***now***.

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